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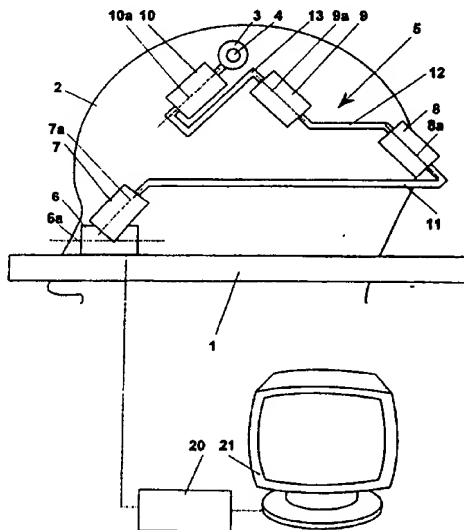
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(54) Title: APPARATUS FOR GUIDING AND SUPPORTING AN INSTRUMENT SUCH AS A SURGICAL INSTRUMENT OR A PROBE

(57) Abstract

An apparatus for the guide of a surgical instrument (4), in particular for skull neurosurgery, coupled to a stereotactic frame (1) kept integral in use to a patient (2) and to a support (3) for said instrument (4). The support (4) or flange is connected to the stereotactic frame (1) by means of a plurality of rotating supports (7, 8, 9, 10) linked in turn by stiff arms (11, 12, 13), each support allowing to said guide apparatus (5) a degree of freedom about an axis of rotation (7a, 8a, 9a, 10a). In particular, the first and second support (7, 8) permit to the instrument a substantially spherical movement with respect to the stereotactic frame (1) and the third and fourth support permit to the instrument (4) a rotation in a plurality of directions with respect to the first and second support (7, 8). The apparatus can act as reader of the position of the instrument in combination to a morphological map on a computer monitor (21) and as support for it, allowing its light manoeuvre in the nearby of a chosen position. It is possible to lock the instrument and the rotating supports in a chosen position.



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TITLE

APPARATUS FOR GUIDING AND SUPPORTING AN INSTRUMENT SUCH AS
A SURGICAL INSTRUMENT OR A PROBE.

DESCRIPTION5 Field of the invention

The present invention generally relates to the field of medical apparatus, and more precisely it relates to an apparatus for guiding and supporting an instrument such as a surgical instrument or a probe .

10 Description of the prior art

Many types of medical instruments, and in particular instruments for neurosurgery, are used by the surgeon with the aid of morphological data obtained by radiographs, computerised tomography and magnetic
15 resonance imaging, obtained with respect to a reference system.

More precisely, the surgeon is guided by hardware systems which store the position of the instrument and trace such position in said reference system, run by a
20 graphic computer. The apparatus which stores the position of the surgical instrument has to detect continually every new position of the instrument during the operation.

In the particular case of skull neurosurgery
25 instruments, the reference system which is common both to the morphological imaging and to the operation steps is normally a stereotactic frame kept integral to the skull of the patient. Generally speaking, such reference system is formed by reference points or reference
30 surfaces which are common to both the steps of imaging and operation.

In a first type of known apparatus, the calculation of the position of the instruments is carried out through

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three dimensional coordinates readers, having a mechanic structure with many degrees of freedom. In another type of known apparatus, the calculation of the position of the instruments is carried out by means of optical systems which are able to determine the coordinates of reference points viewed by telecameras.

None of such existing apparatus, however, is capable of reading the instrument position and, at the same time, to support it in the nearby of a predetermined location.

Summary of the invention

It is an object of the present invention to provide a surgical apparatus which can act as reader of the position of an instrument, such as a surgical instrument or a probe, and to support it at the same time allowing its manoeuvre in the nearby of a chosen position.

It is another object of the invention to provide a apparatus for guiding and supporting such a instrument, which allows a light movement of the instrument, a precise guide of the movement, with possibility of locking it in a chosen position.

It is a further object of the invention to provide an apparatus for guiding and supporting an instrument such as a surgical instrument or a probe which, in use, have structure which minimizes the forces for locking it in the chosen positions, reducing also at the minimum the weight and the encumbrance of braking elements provided therefor.

It is a particular object of the invention to provide an apparatus which can aid the surgeon in the course of skull neurosurgery, and which guides the instruments in a spherical region concentric to the skull of the patient.

These and other objects are accomplished by the

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apparatus according to the invention, as defined by the attached claims.

Brief description of the drawings

The characteristics and advantages of the apparatus according to the present invention will be made more apparent in the description which follows of one of its possible embodiments, given as examples, but not limitative, with reference to the attached drawings, in which:

- 10 - figure 1 shows diagrammatically an apparatus according to the invention, mounted on a stereotactic frame and connected to a computer;
- figure 2 shows a perspective side view of a preferred embodiment of the apparatus of figure 1;
- 15 - figure 3 shows a rear perspective view of the guide apparatus of figure 2 disengaged with respect to the stereotactic frame;
- figure 4 shows an elevational side view of the preferred embodiment of the apparatus according to the invention;
- 20 - figure 5 shows a perspective elevational view of the apparatus of figure 4.

Description of the preferred embodiments

With reference to figure 1, an apparatus for the guide of a surgical instrument for skull neurosurgery, is
25 combined with a stereotactic frame 1, belonging to a stereotactic appliance (see fig. 5), suitable for engaging with the skull of the patient 2 through known means not shown, and a support flange 3 for a surgical instrument 4.

30 Flange 3 is connected to the stereotactic frame 1 through a guide apparatus 5 according to the present invention. More precisely, guide apparatus 5 is connected to stereotactic frame 1 by means of a fastening device 6, which is easily releasable and comprises a pivot axis 6a

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about which an external part of it is able to rotate. Pivot axis 6a, in the present case, is substantially parallel to the plane of the stereotactic frame 1. Releasable fastening device 6 comprises mechanical lock
5 means of the rotation about pivot axis 6a at a precise reference position, to be set as zero position. Flange 3 is then connected to fastening device 6 through a plurality of pivotal supports, respectively a first, a second, a third and a fourth pivotal support 7, 8, 9, 10,
10 connected in turn to one another by means of stiff arms 11, 12, 13. The fourth support 10 is connected directly to flange 3, preferably through a further arm 14.

As better shown in figure 2, supports 7, 8, 9 and 10 permit the rotation of their proximal parts with respect
15 to their distal parts about respective axes 7a, 8a, 9a and 10a, as indicated by the corresponding arrows. By virtue of this structure, instrument 4, whose axis is indicated with numeral 15, has four degrees of freedom, one for each support, and can then be guided in many positions with
20 respect to the skull 2 of the patient. Moreover, guide apparatus 5 has a further degree of freedom given by the rotation about axis 6a (fig. 3), which normally is not used except at the beginning or end of an operation step when moving the instrument towards or away from the
25 patient.

Each support 7, 8, 9 and 10 have, in addition to the possibility of rotation between a proximal element and a distal element, a sensor of the angular position between the proximal and the distal element as well as a brake for
30 locking the rotation of the distal element with respect to the proximal element. A preferred embodiment of the third support 9 is illustrated in figure 4 and described below.

As shown in figure 1, the signal responsive to the angular positions both of releasable fastening device 6,

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which has the function of zero reference, and of each support 7, 8, 9, 10, is sent to a computer 20 connected to a monitor 21 on which the position of instrument 4 is traced with respect to a plurality of maps imaged in a known way by a preliminar morphological analysis of the patient, as above synthetically described.

In a possible way of use of the apparatus according to the invention, stereotactic frame 1 is set integral to the patient 2. Once the surgeon has unlocked the rotation of the supports 7, 8, 9, 10 (for example by a pedal not shown) he can guide instrument 4 freely and with minimum effort. Then, the surgeon can lock the guide apparatus in a chosen position where he can use correctly the instrument 4 in the direction of operation. The corresponding signals which are sent to computer 20 are responsive the position of the image of the instrument shown on monitor 21 calculated with reference to both stereotactic frame 1 and the stored maps.

Apparatus 5 permits the movement of instrument 4 with respect to only a portion of skull 2, that is a spherical area, for example +/- 40 degrees about a central position initially fixed when setting fastening device 6 to stereotactic frame 1. Therefore, in order to operate in different areas of the skull, a plurality of connection points 16 are provided for in different positions of the stereotactic frame 1, shown in figure 2 and comprising hole 17 for a socket not shown and a reference tooth 18. Alternatively, bayonet connections may be provided for. In the example of figure 2 only eight different connection points 16 of apparatus 5 have been provided for, of which only five are shown in addition to that to which the apparatus is actually fixed.

As shown in figure 3, the apparatus 5 can be easily set in a position of minimum encumbrance with respect to

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the skull 2 of the patient, simply rotating it about axis 6a of fastening device 6. In the position of figure 3, moreover, apparatus 5 can be removed or it can be later set again in the position of figure 2 to start a new step of the operation on skull 2.

With reference to figures 4 and 5, according to a preferred embodiment of the invention, in order to reduce the weight of the apparatus and to optimise the movement of arms 11, 12 and 13, their axes 7a, 8a, 9a and 10a are two by two incident, respectively in points O, A and B. In this way, in fact, the moment of the forces which pass through point O is equal to zero. This is advantageous because the brake of each support has not to bear such moment when the apparatus is locked and can then be made smaller without reducing the braking capability.

According to a particularly advantageous embodiment of the invention, the point of incidence of the axes 7a and 8a is located at the centre of the skull of the patient. In this way the free end of the instrument 4 describes a spherical portion concentric to the skull.

Moreover, preferably, the length and the shape of arms 11, 12 and 13 is chosen in such a way that the straight line of the resultant of the weight forces of the apparatus 5 passes through point O. In this way, if the patient's skull is located in such a way that the straight line BO is vertical, also the moments of the weight forces of all the supports is equal to zero, further reducing the forces acting on the apparatus when locked. Therefore, since the moments of the weight forces do not stress the supports, the weight of all the instrument 4, which can be low or also high, weighs directly on the stereotactic frame 1, thus not affecting the braking capability of supports 7, 8, 9, 10.

A particular advantage of the preferred embodiment

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of figures 4 and 5 is that the distances AO, BO and AB of figure 4 are constant, as well as the angles of triangle OAB are constant, thus allowing to apparatus 5 to guide specifically instrument 4 about the skull 2. A further preferred aspect is that the supports 9 and 10 have point of incidence B on the axis 15 of instrument 4. Therefore, the rotation about axes 9a and 10a is actually a movement of instrument 4 inside a cone having vertex at point B which is located on axis 15. Vertex B, therefore, describes a spherical portion having centre in O, and the apparatus 5 obtains the result of correctly guiding instrument 4 during skull neurosurgery.

A preferred embodiment of the connection of the fastening device 6 to stereotactic frame 1, shown always in figures 4 and 5, comprises a dovetailed coupling 22, which is steady and easily releasable. Similarly to what shown in figure 3, moreover, guide apparatus 5 can be rotated about pivot 6a of fastening device 6 in order to be arranged in a position of minimum encumbrance. In order to make easier this rotation, a release lever 30 (figures 4 and 5) locks or unlocks pivot 6a of fastening device 6.

The embodiment of figure 5 may be equipped with means of known type for keeping the apparatus 5 integral to the skull 2 of the patient, comprising pins 23 which extend from stereotactic frame 1.

In figure 4 is then shown a cross sectional view of a possible structure of third support 9, which is substantially the same as the other supports 7,8,10. Support 9 comprises an electromagnetic element 24, linked to the distal portion 9b of the support 9 by means of a spring 24a having high torsional stiffness and high flexibility in the direction of axis 9a. Moreover, it comprises a locking element 25, integral to the proximal portion 9c of support 9. Electromagnetic element 24, in

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normal conditions, is a permanent magnet and is very close to locking element 25 thus contacting disk clutch 26, and locking support 9, proximal portion 9c is prevented from rotating with respect to distal portion 9b. When
5 electromagnetic element 24 is energized, it moves away from locking element 25 thus temporarily unlocking support 9 and permitting the rotation of proximal portion 9c with respect to distal portion 9b. In figure 4 is also shown an angular position sensor 27. As a person skilled in the art can
10 easily understand, single disk element 26 and locking element 25 can be replaced in a known way by multiple disk and multiple locking elements coaxial and alternate to one another, so that the braking capability is increased.

Advantageously, instrument 4 can slidably engage
15 with flange 3, freely moving in the direction of arrow 15a of figure 4. Inside flange 3, in fact, an encoder (not shown) may be provided for measuring the relative position of the proximal end of the instrument 4 with respect to point B, or another reference point. Instrument 4,
20 moreover, can either be kept locked with respect to flange 3, or it can be freed. In this second case, the surgeon uses the apparatus according to the invention only as unidirectional guide for the instrument, but not as a support for it. In other words, by putting instrument 4
25 in the flange 3 of apparatus 5 when unlocked, it is possible to control the exact position of instrument 4 which is totally handled by the surgeon, which does not lose its control, thanks to the light movement of the supports 7,8,9,10. At the same time, the surgeon checks
30 the direction of the instrument on the monitor 20, until it exactly coincides with the operation area. Then, after having locked the guide apparatus 5, the surgeon has only to control the movement of the instrument 4 according to arrow 15a of figure 4, viewing on the monitor its position

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within the operation area.

Finally, even if in the attached drawings reference has been made to skull surgery, it is clear that the stereotactic frame 1 can be conformed to other parts of the
5 body

The foregoing description of the specific embodiments will so fully reveal the general nature of the invention that others can, by applying current knowledge, readily modify and/or adapt for various
10 applications such specific embodiments without undue experimentation and without departing from the generic concept, and, therefore, such adaptations and modifications should and are intended to be comprehended within the meaning and range of equivalents of the
15 disclosed embodiments. The means and materials for carrying out various disclosed functions may take a variety of alternative forms without departing from the invention. It is to be understood that the phraseology or terminology employed herein is for the purpose of
20 description and not of limitation.

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CLAIMS

1. Apparatus for the guide of an instrument, such as a surgical instrument or a probe, coupled to a stereotactic frame kept integral in use to a patient and to a support for said instrument, characterised in that said support is connected to said stereotactic frame by means of a plurality of rotating supports linked in turn by stiff arms, each support allowing to said guide apparatus a degree of freedom about an axis of rotation.
- 10 2. Apparatus according to claim 1, wherein said apparatus comprises a first, a second, a third and a fourth support linked in turn to one another by means of respective stiff arms, said first and second support permitting to said instrument a substantially spherical movement with respect to said stereotactic frame and said third and fourth support permitting to said instrument a rotation in a plurality of directions with respect to said first and second support.
- 20 3. Apparatus according to claim 2, wherein said axes of rotation of said first, second, third and fourth support are, in turn, two by two incident.
4. Apparatus according to claims 2 or 3, wherein said stereotactic frame is kept integral to the skull of a patient, said axes of rotation of said first and second support being incident at the centre of said skull, said instrument describing a spherical portion concentric to said skull
- 25 5. Apparatus according to claims 2, 3 or 4, wherein the length and the shape of said arms, which in turn connect said supports to each other, is such that the straight line of the resultant of the weight forces of said apparatus passes through the point of incidence of the axes of rotation of said first and second support.
- 30 6. Apparatus according to any of claims from 2 to 5,

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wherein said axes of rotation of said third and fourth support are incident on the axis of said instrument.

7. Apparatus according to the previous claims, wherein said rotating supports comprise

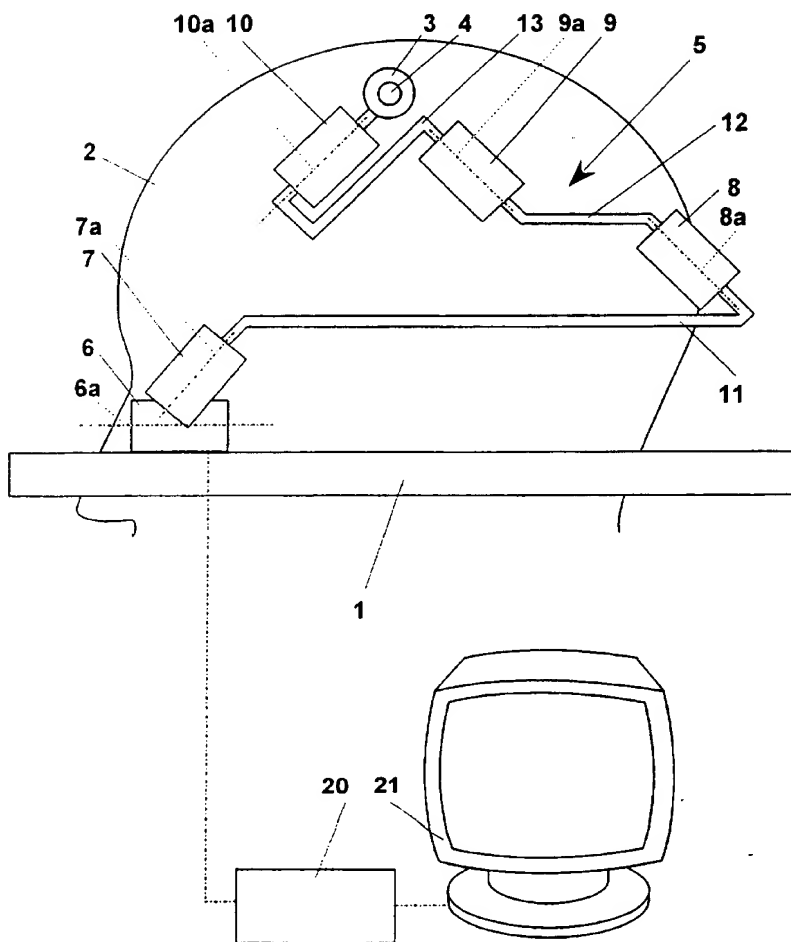
- 5 - a pivotal coupling between a proximal element and a distal element,
 - a sensor of the angular position between said elements with respect to said axis of rotation and
 - a brake for locking or freeing the rotation between
- 10 said elements.

8. Apparatus according to claim 7, wherein said brake comprises a first portion integral to said distal element and a second portion integral to said proximal element, said first and second portion contacting each other

15 further to movement of an electromagnetic element.

9. Apparatus according to the previous claims, wherein said instrument is slidably coupled to said support, sensor means of the relative position between said instrument and said support being provided for.

20 10. Apparatus according to previous claims, wherein a fastening device for a pivotal and releasable connection with said stereotactic frame is provided for, on the latter a plurality of spaced connection elements for said fastening device is provided for.

Fig. 1

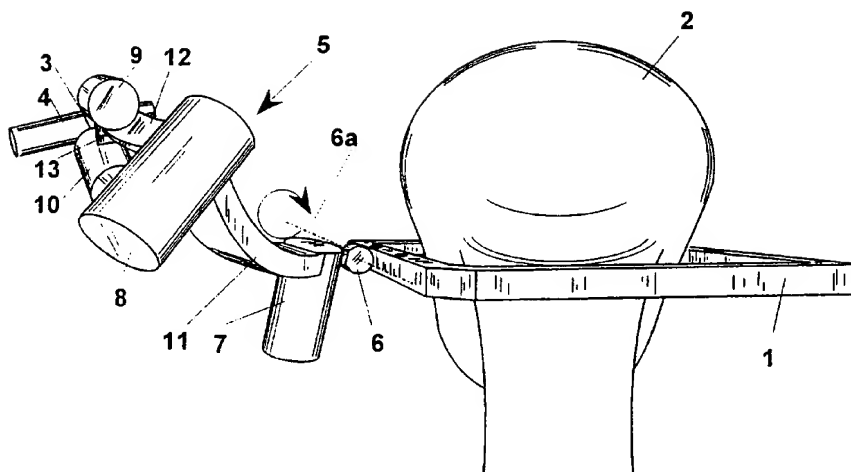
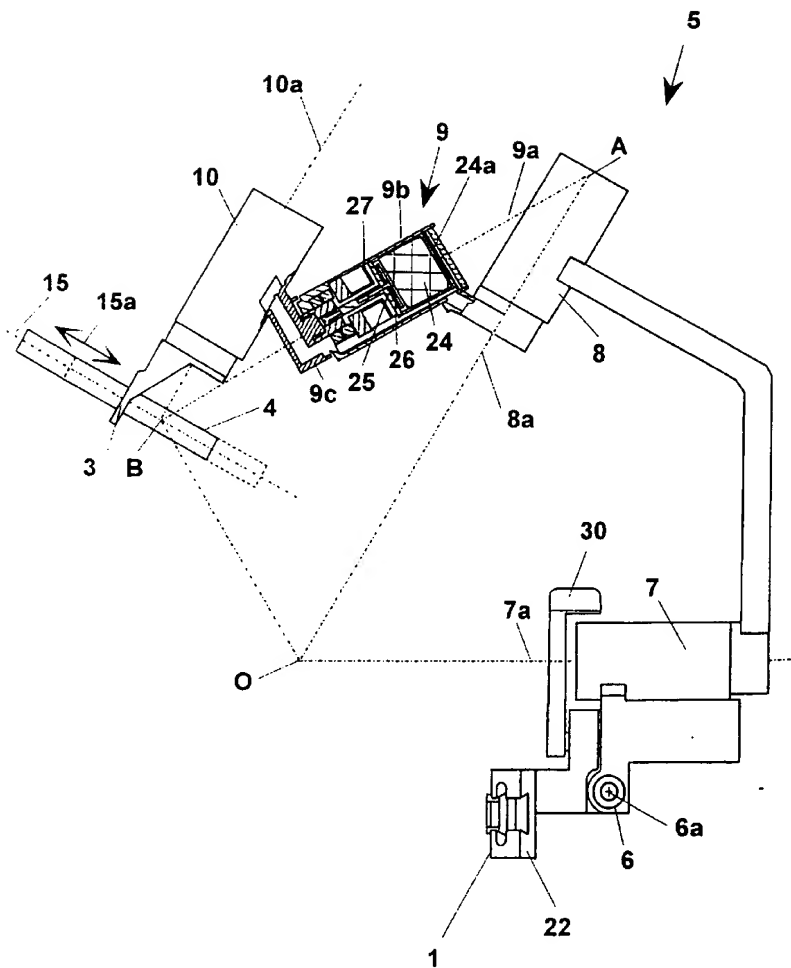


Fig. 3

Fig. 4

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/EP 97/06932

A CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61E

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 10368 A (NOMOS CORP) 11 April 1996 see page 6, line 11 - page 8, line 7; figure 1 ---	1,2,7,10
X	WO 95 13758 A (D'URSO PAUL STEVEN) 26 May 1995 see page 10, line 9 - line 17; figures 1,3 ---	1,2,7
A	US 5 050 608 A (WATANABE EIJU ET AL) 24 September 1991 see abstract; figures 1,2 ---	1,2,4-7
A	US 5 230 623 A (GUTHRIE BARTON L ET AL) 27 July 1993 see column 3, line 14 - column 5, line 36; figures 1,2 --- -/-	1,2,7

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A	US 4 548 373 A (KOMURA SEIICHI) 22 October 1985 see the whole document ---	1,7,8
A	US 5 494 034 A (SCHLOENDORFF GEORG ET AL) 27 February 1996 see column 4, line 38 - column 6, line 51; figure 6 -----	1-10

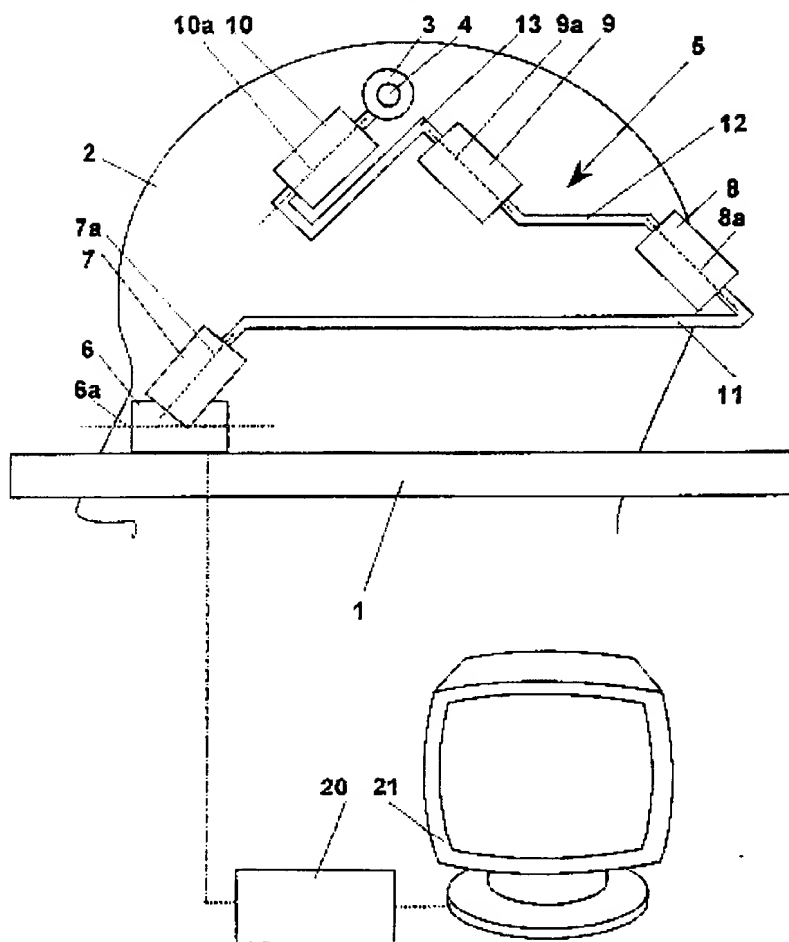
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern. al. Application No
PCT/EP 97/06932

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9610368 A	11-04-96	US 5695501 A AU 3760895 A EP 0783279 A	09-12-97 26-04-96 16-07-97
WO 9513758 A	26-05-95	AU 675179 B AU 7934794 A EP 0729322 A	23-01-97 06-06-95 04-09-96
US 5050608 A	24-09-91	NONE	
US 5230623 A	27-07-93	NONE	
US 4548373 A	22-10-85	CH 662719 A DE 3410417 A	30-10-87 04-10-84
US 5494034 A	27-02-96	DE 3717871 A AU 621053 B AU 1805688 A CA 1325850 A CA 1336923 B DE 3884800 D WO 8809151 A EP 0359773 A KR 9701431 B US 5186174 A	22-12-88 05-03-92 21-12-88 04-01-94 05-09-95 11-11-93 01-12-88 28-03-90 06-02-97 16-02-93

Fig. 1

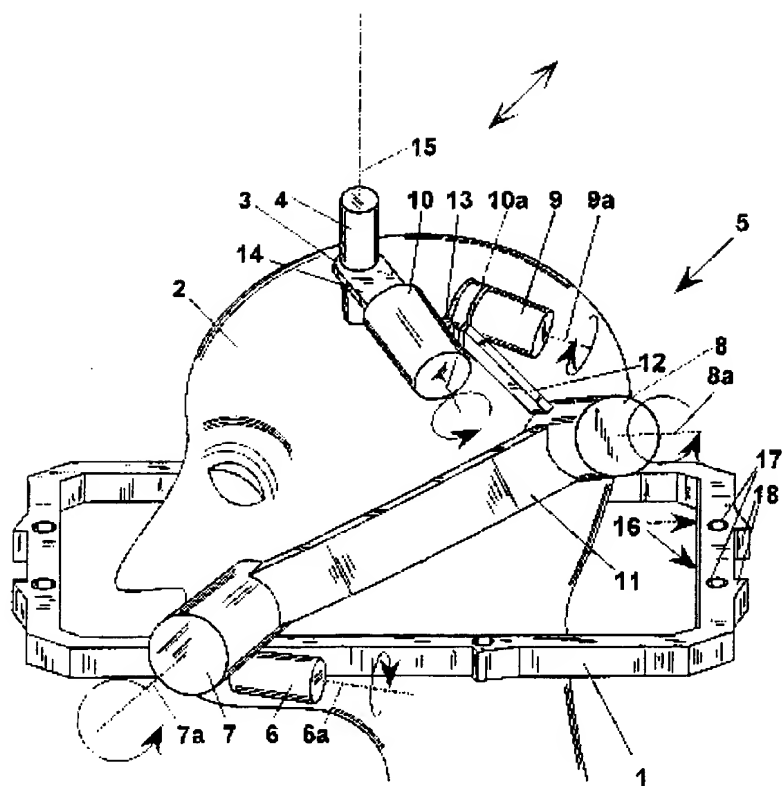


Fig. 2

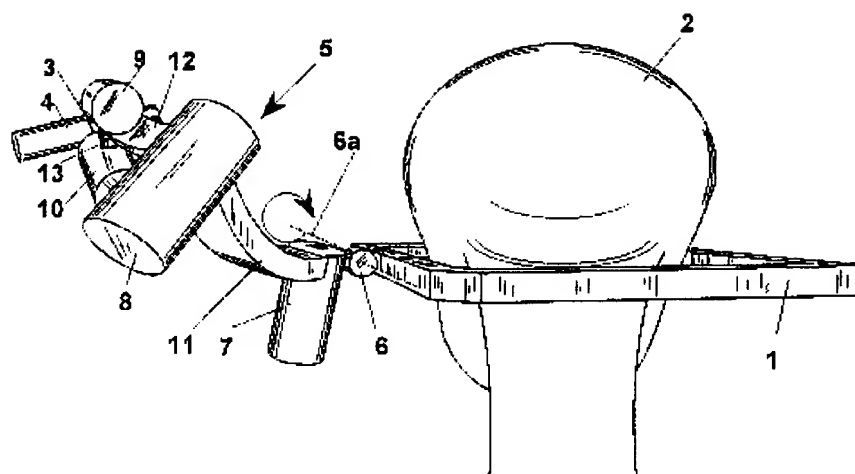
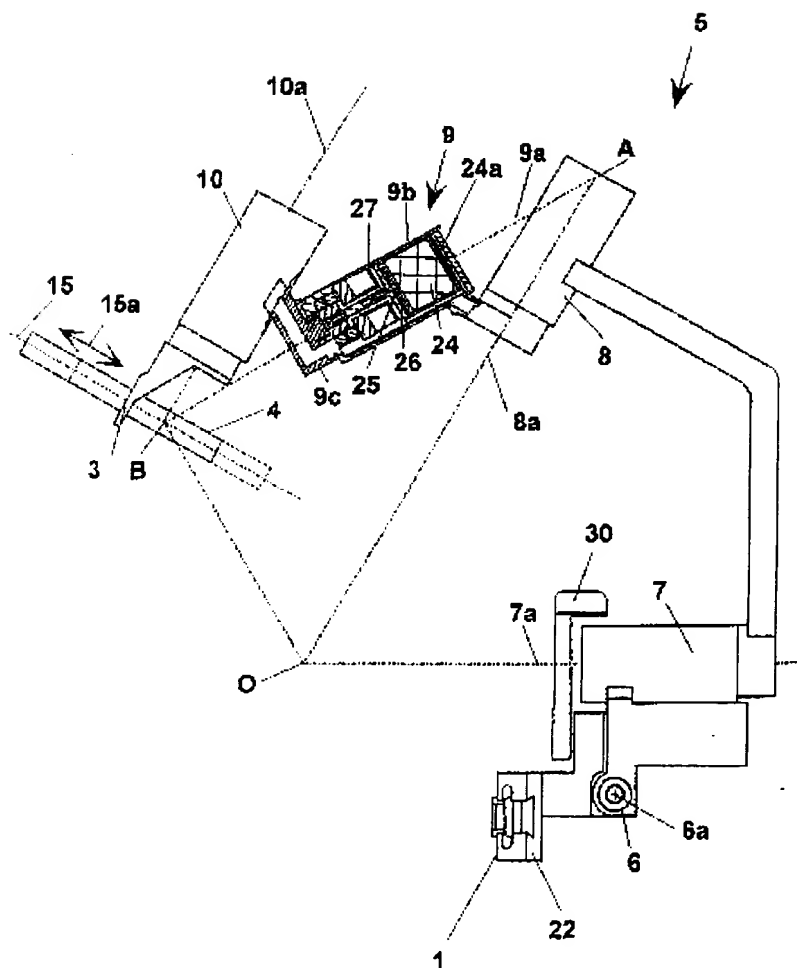
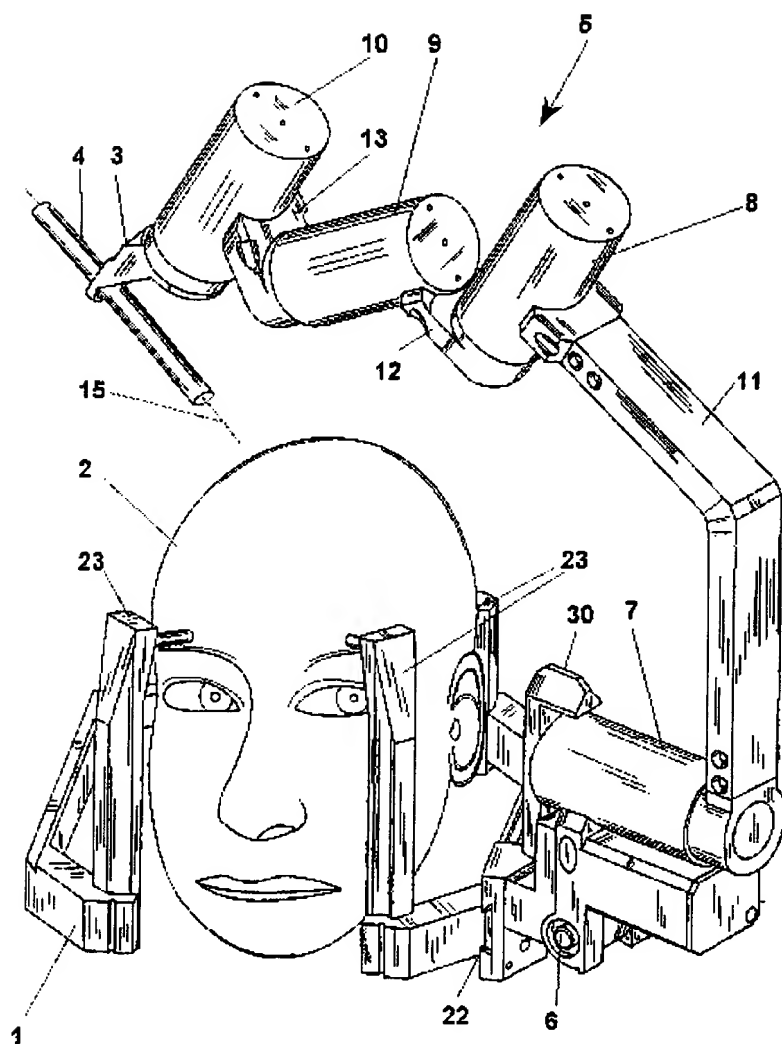


Fig. 3

Fig. 4



**Fig. 5**